

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

**Express Scripts, Inc., and  
Express Scripts Senior Care Holdings, Inc.,**

Plaintiffs,

v.

**kaléo, Inc.,**

Defendant.

Case No. 4:17-cv-01520-RLW

**Jury Trial Demanded**

**Answer to Defendant's Counterclaims (Redacted)**

Plaintiffs and counterclaim defendants Express Scripts, Inc., and Express Scripts Senior Care Holdings, Inc. (together “**Express Scripts**”) answers the Counterclaims filed by kaléo, Inc. (“**kaléo**”), as follows, using numbered paragraphs that correspond to the numbered paragraphs of the Counterclaims<sup>1</sup>:

1. This paragraph incorporates the preceding paragraphs from kaléo’s Answer. To the extent a response is required, Express Scripts incorporates the corresponding allegations in its Complaint, ECF 1.

2. Denied, except that Express Scripts admits that Evzio is a life-saving medication, but Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegation that Evzio has saved thousands of lives since 2014.

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<sup>1</sup> The Counterclaims use headings that are not contained in number paragraphs and therefore do not require a response. To the extent these headings are deemed allegations requiring a response, they are denied.

3. Denied, except that Express Scripts admits that it entered into rebate agreements with kaléo, in which kaléo agreed and expressly acknowledged that it owed rebates and administrative fees to Express Scripts [REDACTED]

4. Denied, except that Express Scripts admits that, as a result of kaléo increasing the price of Evzio by over 500% (from \$575 for a two-pack of injectors in 2014 to \$3750 in 2016), and in light of the availability of significantly cheaper alternatives to Evzio that are clinically equivalent (such as the nasal spray Narcan, which costs only about \$150), it decided in early 2016 to exclude Evzio from its National Preferred Formulary, effective July 1, 2016.

5. Denied.

6. Denied.

7. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

8. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

9. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations, except that Express Scripts admits that Evzio contains naloxone, an opioid antagonist.

10. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

11. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

12. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

13. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

14. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations, except that Express Scripts admits that the FDA approved Evzio in 2014.

15. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations, except that Express Scripts admits that the FDA approved Narcan in 2015.

16. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

17. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

18. Denied. To the extent kaléo is relying on the documents cited in footnotes 26 and 27, they speak for themselves.

19. Denied, except that Express Scripts admits that as a pharmacy benefit manager, it manages prescription drug benefits pursuant to contracts with its clients, which include managed care organizations, health insurers, employers, and unions, and that it negotiates with pharmaceutical manufacturers for rebates.

20. Denied.

21. The last sentence is denied. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

22. Denied. To the extent kaléo is relying on the statement cited in footnote 28, the statement speaks for itself.

23. Denied, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations about other PBMs, and except that Express Scripts admits that, as a pharmacy benefit manager, it manages prescription drug benefits pursuant to contracts with its clients.

24. Denied, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations about other PBMs, and except that Express Scripts admits that it enters into separate contracts with its clients and with retail pharmacies. Those contracts include negotiated rates among other terms.

25. Denied, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations about other PBMs, and except that Express Scripts admits that it pays certain pharmacies in accordance with its contracts with those pharmacies, and that it is paid by its clients in accordance with its contracts with those clients.

26. Denied.

27. Denied, except that Express Scripts admits it entered into rebate agreements with kaléo, as alleged in paragraphs 7 and 29 of the Complaint.

28. Denied, except that Express Scripts admits that health plans usually do not provide coverage for every prescription drug available in the market; instead, health plans often develop a clinically sound list of covered drugs, called a “formulary,” and provide varying degrees of coverage for drugs on that formulary. Express Scripts further admits that when multiple drugs compete with each other, a formulary may prefer certain of those drugs over the others and provide that the favored drugs have a lower co-pay or coinsurance than the non-

avored drugs. Health plans may further distinguish between non-preferred drugs by placing extra restrictions on their usage, such as requiring step edits or prior authorizations.

29. Denied, except that Express Scripts admits that health plans decide for themselves what drugs to include on their own formularies and what level of preference to assign them.

30. Denied, except that Express Scripts admits that it publishes a National Preferred Formulary and that health plans may choose to adopt the National Preferred Formulary in whole or in part.

31. Denied, except that Express Scripts admits that it identifies certain drugs that are excluded from the National Preferred Formulary because clinically equivalent alternatives are available at a significant cost savings, and that health plans are free to choose to adopt this exclusion list in whole or in part.

32. Denied.

33. Denied, except that Express Scripts admits that the number of drugs excluded from the National Preferred Formulary was approximately 48 in 2014, 66 in 2015, 87 in 2016, and 85 in 2017, and except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations about exclusions by CVS Health or OptumRx.

34. Denied.

35. Denied, except that Express Scripts admits that, as a result of kaléo increasing the price of Evzio by over 500% (from \$575 for a two-pack of injectors in 2014 to \$3750 in 2016), and in light of the availability of significantly cheaper alternatives to Evzio that are clinically equivalent (such as the nasal spray Narcan, which costs only about \$150), it decided in early 2016 to exclude Evzio from its National Preferred Formulary, effective July 1, 2016.

36. Denied. To the extent kaléo is relying on the statements or lawsuit cited in footnotes 30–32, they speak for themselves.

37. Denied.

38. Denied.

39. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

40. Admitted, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the end for which kaléo set the initial list price of Evzio, and that the full name of the PSG Agreement is “Preferred Savings Grid Rebate Program Agreement” and that the full name of the “Medicare Rebate Agreement” is “Medicare Part D Rebate Program Agreement.”

41. Denied.

42. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

43. Denied. The Rebate Agreements contain the passage quoted by kaléo, but kaléo has misleadingly excerpted that passage to omit a sentence that [REDACTED]

[REDACTED]

[REDACTED].

44. Denied, except that Express Scripts admits that the Rebate Agreements provide that [REDACTED]

[REDACTED]

[REDACTED].

45. The first and second sentence are admitted; the third and fourth sentences are denied.

46. Admitted, except that [REDACTED].

47. Denied.

48. Denied, except that Express Scripts admits that the Rebate Agreements do not require Express Scripts to [REDACTED]  
[REDACTED]

49. Denied.

50. Denied.

51. Denied.

52. Denied, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding an undated prior authorization request by an unnamed physician.

53. Denied.

54. Denied, except that Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence.

55. Denied, except that Express Scripts admits that the invoices from October 2014 through October 2015 did not include any price protection rebates.

56. Express Scripts admits that kaléo raised the list price of Evzio to \$3,750 for a two-pack of injectors in February 2016. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

57. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

58. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

59. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

60. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of these allegations.

61. Express Scripts admits that under the PSG Rebate Agreement it invoiced kaléo \$101,070.95 for March 2016 and \$5,088,566.19 for April 2016. Express Scripts lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

62. Denied.

63. Denied, except that Express Scripts admits that, as a result of kaléo increasing the price of Evzio by over 500% (from \$575 for a two-pack of injectors in 2014 to \$3750 in 2016), and in light of the availability of significantly cheaper alternatives to Evzio that are clinically equivalent (such as the nasal spray Narcan, which costs only about \$150), it decided in early 2016 to exclude Evzio from its National Preferred Formulary, effective July 1, 2016.

64. Denied.

65. Denied, except that Express Scripts admits that it has correctly not paid kaléo the amounts that kaléo improperly characterizes as overpayments, and that it continues to invoice kaléo for rebates and administrative fees in accordance with the express terms of the Rebate Agreements.

66. Denied, except that Express Scripts (1) admits that kaléo has notified Express Scripts that it will terminate the PSG Rebate Agreement effective December 31, 2017; (2) admits



that kaléo has refused to pay every invoice Express Scripts has sent under the Rebate Agreements from the June 2016 invoice through the present; and (3) lacks knowledge or information sufficient to form a belief as to the truth of the allegation that kaléo “will continue” to refuse paying invoices sent by Express Scripts.

67. Denied.

68. This paragraph incorporates the preceding paragraphs from kaléo’s Answer and Counterclaims. To the extent a response is required, Express Scripts incorporates the corresponding allegations in its Complaint and the corresponding responses in the above paragraphs.

69. Admitted.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied, except that Express Scripts admits that it continues to invoice kaléo for rebates and administrative fees in accordance with the express terms of the PSG Rebate Agreement.

77. Denied.

78. This paragraph incorporates the preceding paragraphs from kaléo’s Answer and Counterclaims. To the extent a response is required, Express Scripts incorporates the

corresponding allegations in its Complaint and the corresponding responses in the above paragraphs.

79. Admitted.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied, except that Express Scripts admits that it continues to invoice kaléo for rebates and administrative fees in accordance with the express terms of the Medicare Rebate Agreement.

87. Denied.

Express Scripts denies that kaléo is entitled to judgment in its favor or to any of the relief it prays for.

#### **First Affirmative Defense**

kaléo fails to state a claim upon which relief may be granted.

#### **Second Affirmative Defense**

kaléo acquiesced to the alleged conduct of which it now complains.

#### **Third Affirmative Defense**

kaléo consented to the alleged conduct of which it now complains.

#### **Fourth Affirmative Defense**

kaléo ratified the alleged conduct of which it now complains.

**Fifth Affirmative Defense**

kaléo failed to perform its obligations under the Rebate Agreements.

**Sixth Affirmative Defense**

kaléo failed to mitigate its alleged damages.

Dated: July 13, 2017

Respectfully submitted,

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*Attorneys for Plaintiffs Express Scripts, Inc., and  
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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing document was filing using the CM/ECF system, which will automatically provide notice to all attorneys of record by electronic means.

/s/ Sarah Hellman .